# Complete Summary

## GUIDELINE TITLE

Immunizations.

## BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 56 p. [61 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Diphtheria
- Tetanus
- Pertussis
- Poliomyelitis
- Measles
- Mumps
- Rubella
- Pneumococcal disease
- Varicella
- Haemophilus influenza b infection
- Hepatitis B (Hep B)
- Influenza
- Hepatitis A (Hep A)
- Meningococcal infection

### GUIDELINE CATEGORY

Prevention

## CLINICAL SPECIALTY

Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

## INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

- To increase the rate of people up-to-date with recommended immunizations
- To increase the rate of special groups (pediatrics, adolescents, young adults, adults, seniors) up-to-date with specific antigen immunizations
- To reduce missed opportunities for administering immunizations
- To increase the percent of people behind with recommended immunizations with catch-up plans

## TARGET POPULATION

Persons of all ages seeking immunity from infectious diseases through the use of vaccines

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Routine vaccination for infants and children, including:
    - Diphtheria and tetanus toxoids with acellular pertussis (DTaP); diphtheria and tetanus toxoids with whole-cell pertussis (DTP)
    - Inactivated poliovirus vaccine (IPV)
    - Measles, mumps, rubella (MMR)
    - Pneumococcal 7 valent conjugated polysaccharide vaccine (PCV7)
    - Varicella
    - Haemophilus influenzae b (Hib) conjugate vaccine, such as HIBTITER (HbOC), ActHIB or OmniHib (PRP-T), Comvax (PRP-OMP), Pedvax (PRP-OMP)
    - Hepatitis B (Hep B)
2. Special uses vaccines for children or adults, including:
    - Pneumococcal 23 valent polysaccharide vaccine (PPV23)

- Varicella
- Influenza vaccine such as inactivated, injectable influenza vaccine (Fluzone® and Fluvirin®) or live, attenuated influenza vaccine (FluMist®)
- Hepatitis A (Hep A), such as Havrix or Vaqta
- Meningococcal

3. Adult vaccines, including:
    - Varicella
    - Tetanus, diphtheria (Td)
    - Influenza
    - Pneumococcal (PPV23)
    - Hepatitis A
    - Hepatitis B
    - Meningococcal
    - MMR
4. Patient/Parent education
5. Recording of adverse events
6. Development of systems to track the immunization status of patients.

### MAJOR OUTCOMES CONSIDERED

- antibody responses
- incidence of disease or illness
- risk of hospitalization and death

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

No additional descriptions of literature search strategies are available.

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented

below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

Cost-effectiveness of Varicella Vaccine

Three papers which studied the vaccine in use in the general population show that, from a medical perspective only, it costs somewhat more to immunize than not. When the additional cost of lost wages is added, immunizing becomes far more cost effective than not doing so. A single paper has studied the vaccine's use among immune-compromised patients. Immune-compromised patients suffer considerably greater side effects from the vaccine and much higher morbidity and mortality from the wild chickenpox virus. When analyzed either with direct medical costs only or with the addition of lost wages, immunizing is more cost effective than not immunizing.

It is cost effective to do immune status testing for all persons 13 years old and older who believe they are nonimmune before they are vaccinated. More than 75% of them will be immune. The prevaccine testing will also reduce substantially the average number of needle sticks that patients in this age range need. For most that number will be only one.

Cost-effectiveness of Tetanus-diphtheria Booster

A schedule of a single tetanus-diphtheria (Td) booster dose between 50 and 65 years has recently been considered cost effective, but evidence about the adequacy of protection against diphtheria with this approach is currently lacking.

## METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its

operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

### Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

### Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The recommendations for immunizations are presented in the form of immunization schedules and an algorithm with a total of 26 components accompanied by detailed annotations. Clinical highlights and immunization schedules are provided below for: Routine Immunization Schedule for Infants, Children, and Adolescents; Special Uses Immunization Schedule for Infants, Children, and Adolescents; Adult Immunization Schedule -- Routine and High Risk. An algorithm for In-Clinic Immunization is provided in the original guideline document.

#### Clinical Highlights

1. Utilize all clinical encounters as opportunities to assess a patient's immunization status. (Annotation #14 - see the original guideline document)

2. Administer at each clinical encounter all immunizations that are due or overdue unless true contraindications exist. (Annotations #17, 18, 23 - see the original guideline document)
3. Educate patients and parents regarding the importance of immunizations, the recommended schedule and options, and the need to maintain a personal record of immunizations and childhood diseases. (Annotations #18, 20 - see the original guideline document)
4. Document reasons for not administering immunizations that are clinically indicated, and flag the record for a recall appointment. (Annotations #22, 25, 26 - see the original guideline document)
5. Document the future plan for administering immunizations. (Annotation #25 - see the original guideline document)

Notice from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): There has been and will be again in the future shortages and delays in the distribution of many of the recommended vaccines. The situation varies by location and health care provider. The work group recommends that all practitioners be kept abreast of the latest national information on vaccine shortage by accessing the CDC's website at www.cdc.gov/nip/news/shortages/default.htm.

Routine Immunization Schedule for Infants, Children, and Adolescents

| Vaccine | Birth | 1 mo | 2 mos | 4 mos | 6 mos | 12 mos | 15 mos | 18 mos | 4-6 yrs | 12 yrs |
|---|---|---|---|---|---|---|---|---|---|---|
| DTaP | | | X | X | X | X | | | X | adult Td |
| IPV | | | X | X | X | | | | X | |
| MMR | | | | | | X | | | X | |
| Pneumococcal (PCV7) | | | X | X | X | X | | | | |
| Varicella | | | | | | X | | | | |
| Hib | | | X | X | X | X | | | | |
| Hep B Schedule 1 | X | X | | | X | | | | | |
| Hep B Schedule 2 | | X | | X | X | | | | | |

Abbreviations: DTaP, diphtheria, tetanus, acellular pertussis; Hep B, hepatitis B; Hib, Haemophilus influenzae type b; IPV, inactivated poliovirus vaccine; MMR, measles, mumps, and rubella

Special Uses Immunization Schedule for Infants, Children, and Adolescents

| Vaccine | 6 mos | 12 mos | 2 yrs | 3 yrs | 4-6 yrs | 13-18 yrs |
|---|---|---|---|---|---|---|
| Pneumococcal | See Annotation #4 | | | | | |
| Varicella | | | Immunize if not previously immunized or no previous history of chicken pox | | | If no history of chickenpox do titre |
| Influenza | X (annual) | | | | | |
| Hep A | | | X (see Annotation #10 in the original guideline document) | | | |
| Meningococcal | | | | | | X |

Abbreviations: Hep A, hepatitis A

For additional information on immunizing high-risk patients, see Annotation #8 in the original guideline document.

Adult Immunization Schedule - Routine and High-Risk

| Vaccine | 19-39 Years | 40-64 Years | 65 Years and Older |
|---|---|---|---|
| Td | Booster every 10 years | | |
| MMR | Persons born after 1956 should have 2 doses measles; additional doses should be given as MMR. | | |
| Pneumococcal (PPV23) | Immunize high risk groups once. Re-immunize those at risk of losing immunity once after 5 years. | | Immunize at 65 if not done previously. Re-immunize once if 1st received >5 years ago and before age 65 |
| Varicella | Persons $\leq$50 with no history of varicella, do titre. If negative, immunize. If >50; assume they are immune. | | |
| Hep B | Universal immunization | Immunize those at high risk. | |

| Vaccine | 19-39 Years | 40-64 Years | 65 Years and Older |
|---|---|---|---|
| Influenza | Annually between Oct-Mar for individuals age 50 and older, those at high risk, and others. | | |
| Hep A | Immunize those in risk groups | | |
| Meningococcal | Immunize those in risk groups | | |

Abbreviations: Hep A, hepatitis A; Hep B, hepatitis B; MMR, measles, mumps, rubella; Td, tetanus, diphtheria

For additional information on immunizing high risk patients, see Annotation #8 in the original guideline document.

### CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided in the original guideline document for in-clinic immunizations.

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The original guideline document contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations. In addition, key conclusions are supported by a conclusion grading worksheet that summarizes the important studies that pertain to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Increased rate of people up-to-date with recommended immunizations
- Increased rate of special groups (pediatrics, adolescents, young adults, adults, seniors) up-to-date with specific antigen immunizations
- Reduced missed opportunities for administering immunizations
- Increased percent of people behind with recommended immunizations with catch-up plans

### POTENTIAL HARMS

Adverse effects (i.e., local reactions, fever, mild forms of disease with attenuated formulations) specific to vaccines

## CONTRAINDICATIONS

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See Appendix C - Guide to Contraindications and Precautions to Immunizations, in the original guideline document for a detailed discussion of contraindications and precautions to immunizations in specific patient populations.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Develop electronic data systems to track the immunization status of patients under the provider's care, with the capability to produce reminders and recalls of upcoming or overdue immunizations. (Annotations #14, 28)
2. Remove barriers to immunization services. (Annotation #14)
3. Develop tracking systems to produce periodic immunization audits for use in developing solutions to identified problems. (Annotations #14, 28)

### RELATED NQMC MEASURES

- Immunizations: percentage of two-year-olds who are up-to-date with their primary series of immunizations (DTaP, IPV, MMR, PCV7, VZV, Hib, Hep B).
- Immunizations: percentage of adolescents who are up-to-date with recommended immunizations (Hep B, MMR, tetanus, and verification of varicella immunity).
- Immunizations: percentage of young adults who are up-to-date with Hepatitis B (Hep B).

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 56 p. [61 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1994 May (revised 2004 Jun)

### GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

## GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health & Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, , Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, , St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

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## SOURCE(S) OF FUNDING

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## GUIDELINE COMMITTEE

Preventive Services Steering Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: James Nordin, MD (Work Group Leader) (HealthPartners Medical Group) (Pediatrics); Emma Carlin, MD (Park Nicollet Health Services) (Family Practice); Gary Konkol, MD (Allina Medical Clinic) (Family Practice); Abinash Virk, MD (Mayo Clinic) (Infectious Disease); Renner Anderson, MD (Park Nicollet Health Services) (Pediatrics); Robert Jacobson, MD (Mayo Clinic) (Pediatrics); Douglas Martin, MD (Park Nicollet Health Services) (Pediatrics); Deborah Meade, RN, (Park Nicollet Health Services) (Health Educator); Rick Carlson, MS (HealthPartners Medical Group) (Measurement Advisor); Sylvia Robinson (Institute for Clinical Systems Improvement) (Implementation Advisor); Nancy Greer, PhD (Institute for Clinical Systems Improvement) (Evidence

Analyst); Jenelle Meyer, RN (Institute for Clinical Systems Improvement) (Facilitator)

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

## GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously released version: Institute for Clinical Systems Improvement (ICSI). Immunizations. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Jul. 51 p.

## GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on August 30, 1999. The information was verified by the guideline developer on October 11, 1999. This summary was updated by ECRI on May 15, 2000 and on October 22, 2001. This summary was updated by ECRI on December 4, 2002. The updated information was verified by

the guideline developer on December 24, 2002. This summary was updated again by ECRI on April 12, 2004 and most recently on September 20, 2004.

## COPYRIGHT STATEMENT



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